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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			DELCOTTO, GREGORY R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/725,233

Applicant(s)

QUENVILLE ET AL.

Examiner

Gregory R. Del Cotto

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-7 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-7, and 18-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 3, 5-7, and 18-27 are pending. Applicant's arguments and amendments filed 10/16/08 have been entered. Claims 2, 4, and 8-17 have been canceled.

Objections/Rejections Withdrawn

The following objections/rejections as set forth in the Office action mailed 4/17/08 have been withdrawn:

None.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(d) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-7, 20-22, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323).

'578 teaches an aqueous composition for cleaning and wetting a contact lens containing a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18, a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, a second non-ionic surface active agent, and wetting agent. See Abstract. The cleaning compositions also include buffering agents such as sodium carbonate. Also, the compositions may contain antimicrobial agents in amounts from 0.00001 to about 5% by weight. Suitable antimicrobial agents include polyhexamethylene biguanide, etc. See para. 23-26. The compositions may also contain a sequestering agent such as EDTA. Additionally, supplemental wetting agents may be used such as methyl cellulose, etc. See para. 22. Groemminger does not teach the use of a polyethyleneterephalate container, or an article of manufacture comprising a container formed from polyethyleneterephalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Asgharian et al teach a two-compartment bottle assembly useful in preparing multi-purpose compositions containing an Al-trypsin and disinfectant. These

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compositions are useful for cleaning and disinfecting contact lenses. See Abstract. The bottle may be made out of materials such as molded polyethylene, polyethyleneterephthalate (PET), etc. See column 5, lines 1-5. The disinfecting compositions generally contain one or more antimicrobial agents, a buffer, tonicity agents, a chelating agent, and surfactants (i.e. block copolymers). See column 11, lines 50-69. Specifically, Asgharian et al contain cleaning compositions containing 0.001% Polyquaternium 1, 0.6% boric acid, 0.1% sodium chloride, 0.05% Tetronic 1304, 0.05 disodium edetate, water, etc. See column 14, lines 25-45.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to package the compositions taught by Groemminger in a polyethyleneterephthalate container, at the time the invention was made, because Asgharian et al teaches the use of a polyethyleneterephthalate container to package similar contact lens cleaning/disinfecting compositions.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, for formulate an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of Groemminger in combination with Asgharian et al suggest an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants,

poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Note that, with respect to the disinfection properties as recited by instant claims 21, 22, and 27, the Examiner asserts that the article of manufacture as suggested by Groemminger in combination with Asgharian et al would have the same disinfection properties as recited by instant claims because Groemminger in combination with Asgharian et al suggest an article of manufacture containing the same container which contains the same components in the same amounts as recited by the instant claims.

Claims 1, 3, 5-7, 19-22, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatia et al (US 6,171,404) in view of Stone et al (US 2002/0039975) and WO99/43363.

Bhatia et al teach contact lens care cleaning compositions comprising carbon dioxide and carbonic acid as a cleansing agent. See Abstract. For example, carbon dioxide could be used as the pressurizing gas in an aerosol can containing purified water, a simple contact lens storage solution, or an aqueous-based multi-purpose contact lens composition, including the commercially available rinsing, disinfecting, and storage solution known as Opti-free or Opti-One Express. See column 2, lines 45-60. The contact lens storage solution containing dissolved carbon dioxide may be packaged in a polyethylene terephthalate (PET) bottle under pressure. See column 3, lines 5-25. As shown in Stone et al, Opti-free express contains 0.001% Polyquaternium-1, 0.45% AMP-95, 0.0005% MAPDA, 0.6% boric acid, 1.2% sorbitol, 0.1% sodium chloride,

0.65% sodium citrate, 0.05% Tetronic 1304, 0.05% disodium edetate, sodium hydroxide, hydrochloric acid, and purified water. See para. 52.

Bhatia et al or Stone et al do not teach the use of PHMB, an amphoteric surfactant or a cellulose derivative such as hydroxyethyl cellulose or an article of manufacture comprising a container made up of polyethylene terephthalate containing a surfactant, PHMB, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

'363 teaches compositions for cleaning and disinfecting contact lenses, wherein the compositions contain a carbonate or bicarbonate salt, a non-carbonate buffer system, an antimicrobial agent, and a nonionic surfactant. Products according to the invention, especially multi-purpose solutions, provide simultaneous disinfection and cleaning of contact lenses including the prevention or removal of protein and lipid deposits and other debris. See Abstract. The compositions may contain an antimicrobial agent such as PHMB, Polyquaternium-1, etc. See page 10, line 5 to page 12, line 15. Additionally, the composition may contain at least one surfactant such as amphoteric, cationic, anionic, or nonionic or combinations thereof. See page 12, lines 20-35. Also, water-soluble viscosity builders may be used which have a tendency to enhance the lens wearer's comfort by means of a film on the lens surface cushioning impact against the eye. Suitable viscosity builders include hydroxyethyl cellulose, etc. See page 14, lines 1-15.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use PHMB in the multi-purpose solution disclosed by Stone et

al, with a reasonable expectation of success, because '363 teaches the equivalence of PHMB to Polyquaternium-1 as an antimicrobial agent in a similar composition and further, Stone et al teach the use of Polyquaternium-1.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an amphoteric surfactant in the multi-purpose solution disclosed by Stone et al, with a reasonable expectation of success, because '363 teaches the use of amphoteric surfactants alone or in combination with nonionic surfactants in a similar composition and further, Stone et al teach the use of a nonionic surfactant.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use hydroxyethyl cellulose in the composition taught by Stone et al, with a reasonable expectation of success, because '363 teaches that the use of hydroxyethyl cellulose in a similar composition have a tendency to enhance the lens wearer's comfort by means of a film on the lens surface cushioning impact against the eye.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate an article of manufacture comprising a container made up of polyethylene terephthalate containing a surfactant, PHMB, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of Bhatia et al in combination with Stone et al and '363 suggest an article of manufacture comprising a container made up of polyethylene terephthalate containing a

surfactant, PHMB, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Note that, with respect to the disinfection properties as recited by instant claims 21, 22, and 27, the Examiner asserts that the article of manufacture as suggested by Bhatia et al in combination with Stone et al and '363 would have the same disinfection properties as recited by instant claims because Bhatia et al in combination with Stone et al and '363 suggest an article of manufacture containing the same container which contains the same components in the same amounts as recited by the instant claims.

Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323) as applied to claims 1, 3, 5-7, 20-22, 24, 26, and 27 above, and further in view of WO99/43363.

Groemminger and Asgharian et al are relied upon as set forth above. However, neither reference teaches the use of an amphoteric surfactant in addition to the other requisite components of the composition as recited by the instant claims.

'363 is relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an amphoteric surfactant in the multi-purpose solution disclosed by Groemminger, with a reasonable expectation of success, because '363 teaches the use of amphoteric surfactants alone or in combination with nonionic surfactants in a similar composition and further, Groemminger et al teach the use of a nonionic surfactants.

Claims 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323) or Bhatia et al (US 6,171,404) in view of Stone et al (US 2002/0039975) and WO99/43363 as applied to the rejected claims above, and further in view of Brincat (US 2002/0162863).

Groemminger, Asgharian et al, Bhatia et al, Stone et al, and '363 are relied upon as set forth above. However, none of these references teach that the polyethylene terephthalate container is clear as recited by the instant claims.

Brincat teaches a refillable container adapted to facilitate the purchase of consumer products and the selective discharge thereof. See Abstract. The containers may be made of polyethylene terephthalate and may contain substances such as contact lens solutions, etc. See para. 85 to para. 130. The containers may be clear allowing for the visual identification of the contents thereof. See claim 11.

It would have been obvious to formulate the PET containers taught by Asgharian et al or Bhatia et al as clear, with a reasonable expectation of success, because Brincat teaches the use of a clear (i.e., transparent) PET container for contact lens solutions and Asgharian et al or Bhatia et al teach the use of PET containers in general.

Response to Arguments

With respect to the rejection of the instant claims under 35 USC 103(a) using Groemminger in combination with Asgharian et al, Applicant states that experimental data has been presented in a new Declaration filed under 37 CFR 1.132 that demonstrates the advantages of packaging a contact lens disinfecting solution that

comprises the recited range of PHMB and one or more of the recited surfactants in a PET bottle compared to packaging the same solution in a HDPE bottle. In response, note that, the Examiner asserts that the Declaration is not sufficient to place the instant claims in condition for allowance. The data presented is not commensurate in scope with the instant claims. For example, the instant claims recite any poloxamer or poloxamine surfactants in any amounts and a range of poly(hexamethylene biguanide) while data presented in the 132 Declaration provides results with respect to only one specific embodiment (test solution 1) containing 1.2 ppm PHMB and 3% nonionic surfactant which is not commensurate in scope with the instant claims. Thus, the Examiner asserts the data presented in the 132 Declaration is not sufficient to show the unexpected and superior properties of the claimed invention in comparison to compositions falling outside the scope of the instant claims.

With respect to the rejection of the instant claims under 35 USC 103 using Bhatia et al in view of Stone et al and WO99/43363, Applicant states that given the highly unexpected differences indicated in the biocidal data presented in the 132 Declaration, any alleged prima facie case of obviousness has been rebutted. Furthermore, Applicant states that polyquaternium-1 and PHMB are chemically different and that one skilled in the art would not be motivated to replace polyquaternium-1 in part or as a whole with PHMB in the composition taught by Bhatia et al. In response, note that, while the data presented in 132 Declaration attempts to show the unexpected and superior results achieved when using a plastic PET bottle for contact lens solution, Bhatia et al teaches the use of a contact lens solution contained within a PET bottle as recited by the instant

claims such that there is no picking and choosing amongst the different plastic bottle materials. Furthermore, the Examiner asserts that '363 is analogous prior art relative to Bhatia et al and that one of ordinary skill in the art clearly would look to the teachings of '363 to cure the deficiencies of Bhatia. '363 is a secondary reference relied upon for its teaching of PHMB. The Examiner asserts that one of ordinary skill in the art clearly would have been motivated to use PHMB in the multi-purpose solution disclosed by Stone et al, with a reasonable expectation of success, because '363 teaches the equivalence of PHMB to Polyquaternium-1 as an antimicrobial agent in a similar composition and further, Stone et al teach the use of Polyquaternium-1. Further, while Applicant states that PHMB and polyquaternium-1 have different chemical structures and therefore have different properties, the Examiner asserts that '363 discloses the Polyquaternium-1 and PHMB together as suitable antimicrobial compounds in a similar contact lens solution and therefore, one of ordinary skill in the art would have a reasonable expectation of success when using PHMB or Polyquaternium-1. Thus, the Examiner asserts that the teachings of Bhatia et al in view of Stone et al and '363 would render the claimed invention obvious under 35 USC 103.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory R. Del Cotto/

Art Unit: 1796

Primary Examiner, Art Unit 1796

/G. R. D./

December 22, 2008